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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/668,789

09/23/2003

Yong D. Zhao

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EXAMINER

ALTER, ALYSSA MARGO

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

06/10/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/668,789	Applicant(s) ZHAO ET AL.	
	Examiner Alyssa M. Alter	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 9-16 and 24-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 17-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 9-16 and 24-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 23, 2009.

Response to Arguments

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a stylet *wire* that is tapered) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Additionally, the Applicant alleges that "the Office Action identifies stylet wire 30 as the j-shaped stylet and stylet housing 36 as the electrical lead" (page 8, lines 1-2). However, this was **not** what was indicated by the examiner or presented in the Office Action on 12/22/08. The replica of figure 6 included in the previous Office Action depicted the two-piece stylet with wire 30 and housing 36 both part of the stylet system. In addition, Dutcher discloses "the combined two-piece stylet taught herein is inserted within the central lumen of the body implantable lead in the normal fashion" (col. 2, lines 54-56). Furthermore, Dutcher depicts the incorporation of the two-piece stylet system into a lead in figure 7.

Therefore, the examiner would like to clarify that stylet housing 36 does **not** constitute an electrical lead. Thus, Dutcher does disclose the employment of an electrical lead with an elongated lumen that is able to slidably receive the 2-piece stylet system.

As to the rejection under Williams, the Applicant has argued that Williams does not show a "pre-formed j-shape". This fact was already acknowledged by the examiner on page 3 of the Office Action dated 12/22/08, "Williams does not disclose a preformed j-shape". The Applicant additionally argues that there would be no showing of obviousness to try a pre-formed j-shape stylet and that there was no teaching, suggestion or motivation to employ a pre-formed j-shape stylet. However, as previously stated, employing a j-shaped stylet would enhance navigation and maneuverability within the arterial system, as well as, reduce the risk of trauma. Therefore, it would be obvious to modify Williams with the well known construction of a j-shape stylet.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

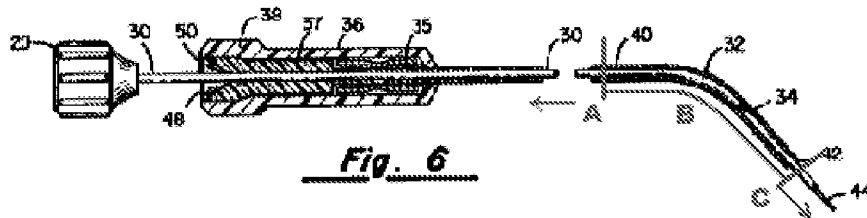
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-4, 8 and 17-20 stand rejected under 35 U.S.C. 102(b) as being anticipated by Dutcher (US 4,381,013). Dutcher discloses a taper zone extending within the curved intermediate segment. Furthermore, Dutcher in figure 6 displays a

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two-piece stylet in a "J" shape (please see below).



The examiner considers the claimed substantially straight proximal segment to be from the proximal end to point A, the curved intermediate segment is defined by segment B (between points A and C) and point C to the tip is considered to be the substantially straight distal segment.

As displayed above in the replica of figure 6, the taper zone, originates in the curved section and decreases or tapers, such as at point 42 and further in the substantially straight distal segment beyond point C. Therefore, Dutcher does disclose a taper zone extending from within the curved intermediate segment.

It is further noted that the claim does not state that the taper is in a curved portion of the curved segment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 5-7 and 21-23 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Dutcher (US 4,381,013) in view of Hartley et al. (US 20040073141 A1). Since Dutcher does disclose a tapered zone extending within the curved intermediate segment, the arguments in regards to claims 5-7, 13-15, 21-23 and 28-30 are considered moot.

Dutcher discloses the claimed invention except for the degree of the curve being approximately 180 degrees, approximately 210 degrees or some value there between. Hartley et al. teaches that it is known to use a curve in the range of 140 to 200 degrees as set forth on page 4, paragraph 68 for navigating within the heart with minimizing damage and irritation to the aortic heart valve. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the curvature as taught by Dutcher with the degree of curvature as taught by Hartley et al., since such a modification would minimize trauma to the vasculature.

As to claims 5, 7, 21 and 23, the examiner considers 200 degrees to be approximately 210 degrees.

2. Claims 1-8 and 17-23 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Williams (US 4,498,482). Williams disclose a tapered stylet for assisting in the placement of a pacing lead as seen in figures 1-3 and 5. However, Williams does not disclose a preformed j-shape. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the

stylelet of Williams with a j-shaped stylelet in order to yield the predictable results of reducing trauma to the arterial system.

As to claims 1 and 17, the well known construction of a j-shape is with a substantially straight distal segment, a curved intermediate segment and a substantially straight distal segment.

As to claims 5-7 and 21-23, the modified Williams discloses the claimed invention except for the specific degree of curvature within the curved segment. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the degree of curvature to yield the predictable results of optimizing the degree of curvature, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (see MPEP 2144.05).

As to claim 8, the modified Williams discloses the claimed invention except for the extendable/retractable helix. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead system with a fixation device, specifically an extendable/retractable helix, to provide the predictable results of engaging the lead into the tissue to maintain intended positioning. Furthermore, the employment of such extendable/retractable helixes is well known in the art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Alyssa M Alter/
Examiner
Art Unit 3762